

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

AVENTIS PHARMACEUTICALS INC. and)	
SANOFI-AVENTIS US LLC,)	
)	
Plaintiffs,)	
)	C.A. No. 06-286 (GMS)
v.)	
)	PUBLIC VERSION
BARR LABORATORIES, INC.,)	
)	
Defendant.)	

**BARR LABORATORIES' RESPONSE
TO PLAINTIFFS' THIRD MOTION *IN LIMINE*
(CONCERNING THE RESPONSIVE EXPERT REPORT OF DR. IAN S. MACKAY)**

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April 7, 2008

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This Court should deny Plaintiffs' motion to exclude the opinions of Dr. Ian Mackay in his responsive report. Dr. Mackay's responsive report is directed to Plaintiffs' assertions of secondary considerations of nonobviousness and was, therefore, timely served within the Court's scheduling order. Moreover, Plaintiffs' claims of overlap ring hollow in view of Barr's repeated representations that it will not present more than one expert on any subject, Plaintiffs' extensive duplication in their own expert reports and Plaintiffs' full opportunity to depose Dr. Mackay on his opinions. Finally, Plaintiffs have not been prejudiced by Dr. Mackay's consideration of a single website page that was inadvertently not disclosed to Plaintiffs.

ARGUMENT

A. Dr. Mackay's Responsive Report Was Timely Served In Response To Plaintiffs' Secondary Considerations Assertions.

The scheduling order expressly permitted Barr to serve reports responding to Plaintiffs' assertions of secondary considerations of nonobviousness. Dr. Mackay's responsive report is

directed to Plaintiffs' secondary considerations assertions and was served on the scheduled date. Accordingly, there is no basis to exclude it.

In response to an interrogatory Barr propounded seeking Plaintiffs' secondary considerations contentions, Plaintiffs have asserted, *inter alia*, that there is (1) a patient preference for the "claimed attributes of Nasacort AQ, such as the drug's thixotropic property, the lack of odor and taste, prompt relief and patient comfort," safety, efficacy and once daily dosing (Ex. R at 65, 66); (2) a "long felt need" for these attributes based on a "persistent problem of patient compliance and dissatisfaction" with nasal sprays (*id.* at 66-67); (3) a failure of others to create a nasal spray with these attributes (*id.* at 69, 72); and unexpected results of safety, efficacy and odorlessness of Nasacort AQ (*id.* at 77-78).

Dr. Mackay's responsive report directly responds to Plaintiffs' secondary considerations contentions, including the opinions of Dr. Eli Meltzer in Dr. Meltzer's rebuttal report. (Pls' Ex. C; Ex. M at ¶¶ 28-39.) While attempting to couch Dr. Meltzer's as opinions on the "odorless[ness]" of prior art products, Plaintiffs have affirmed these opinions of Dr. Meltzer are a basis for their secondary considerations assertions. (Ex. S.) Indeed, sprinkled throughout Dr. Meltzer's entire opinion on "odorless[ness]" are references to "tastelessness," patient compliance and several other "sensory attributes" of nasal sprays. (Ex. M at ¶¶ 28-39.)

The disputed portions of Dr. Mackay's responsive report (paragraphs 5-57 and 66-67) directly respond to these opinions expressed in Dr. Meltzer's rebuttal report, as well as providing opinions regarding the other so called attributes that Plaintiffs say establish secondary considerations.¹ In particular, paragraphs 27-57 of Dr. Mackay's responsive report pertain to Dr.

¹ Paragraphs 66 and 67 of Dr. Mackay's responsive report address Dr. Kaliner's complaints about Dr. Donovan's opening report. They are also, however, directly relevant to Plaintiffs' secondary considerations assertions on the alleged superior deposition pattern of Nasacort AQ

Meltzer's barely-disguised opinion on patient compliance based on sensory attributes, including but not limited to odorlessness. All of the disputed paragraphs also provide the information Dr. Mackay considered in formulating his opinions on long felt need and unexpected results – the two sections that Plaintiffs admit are proper.

Because Dr. Mackay's responsive report is properly directed to secondary considerations, it was timely served in the third round of expert reports.

B. Dr. Mackay's Responsive Report Is Not Duplicative Of Other Barr Experts.

Plaintiffs also attempt to exclude Dr. Mackay's responsive report arguing that it is duplicative of Dr. Thomas Needham's and Dr. Maureen Donovan's expert reports. This is simply not the case. As discussed, Dr. Mackay's responsive report is directed to Plaintiffs' assertions regarding patient compliance, patient preference, long felt need, failure of others and unexpected results, from the perspective of an allergic rhinitis expert. Dr. Needham's expert report addresses prior art disclosures, from the perspective of a pharmaceutical formulator, and his opinions regarding odorlessness do not address the secondary considerations that Dr. Mackay's opinions address. Dr. Donovan's expert report addresses the performance of formulation excipients in the nasal cavity, also from the perspective of a pharmaceutical formulator, and does not address Plaintiffs' secondary considerations.

To the extent there is minor overlap of expert opinions, Barr has made it abundantly clear that it intends to offer only one expert to testify on any subject in accordance with the Final Pretrial Order. (*See* Barr Resp. to Pls' Second MIL, p. 2.) In addition, Plaintiffs continue to offer duplicative testimony from several of their experts. (*Id.* at 2-3.) Plaintiffs had ample opportunity to depose Barr's experts on these opinions and have not been prejudiced or harmed over Flonase and unexpected efficacy based on alleged potency differences between the active ingredients.

by any perceived overlap. Plaintiffs' complaints are therefore without merit and are not a proper basis to exclude Dr. Mackay's opinions. *See Inline Connection Corp. v. AOL Time Warner Inc.*, No. CIV A 02-272 MPT, 2007 WL 61883, at *4-5 (D. Del. Jan. 8, 2007) (refusing to exclude supplemental expert report served three months after close of expert discovery and after expert's deposition and permitting additional deposition of expert).

C. Plaintiffs Were Not Harmed By The Inadvertent Non-Disclosure Of A Single Reference Dr. Mackay Reviewed In Forming His Opinion In Paragraph 11.

Finally, Plaintiffs complain that Dr. Mackay did not disclose a single reference that he reviewed in formulating a five-line paragraph in his responsive report. This non-disclosure was entirely inadvertent and minor, particularly in comparison to Plaintiffs' own conduct. As explained in Defendant's Response to Plaintiffs' First Motion *in Limine*, Plaintiffs introduced new opinions of their experts in the middle of expert depositions. (*See* Barr Resp. to Pls' First MIL, pp. 4-5.)

Dr. Mackay's minor oversight does not establish the sort of harm necessary to exclude his opinion. Moreover, as with their complaints about Dr. Mackay's opening report in their second motion in limine, Plaintiffs made no legitimate attempt, prior to filing the motion to meet and confer with Barr on this issue.² For this reason alone, the Court should deny Plaintiffs' motion. Del. L.R. 7.1.1 (failure to engage in good faith meet and confer "may result in dismissal of the motion").

² In the middle of a meet and confer among the parties on an entirely different topic, Plaintiffs began complaining about Dr. Mackay's reference and demanding either withdrawal of unidentified opinions of Dr. Mackay or a deposition of Dr. Mackay on the information. Barr offered to schedule a future time to meet and confer on the issue. (Ex. T at 2-3.) Plaintiffs responded by filing this motion.

CONCLUSION

For the foregoing reasons, Defendant respectfully requests that the Court deny Plaintiffs' Third Motion *in Limine* and decline to strike the opinions expressed in paragraphs 5-57, 66 and 67 of Dr. Mackay's Responsive Report.

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April 7, 2008

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CERTIFICATE OF SERVICE

I, Karen L. Pascale, Esquire, hereby certify that on April 14, 2008, I caused to be electronically filed a true and correct copy of the foregoing public version document, ***Barr Laboratories' Response to Plaintiffs' Third Motion in Limine (Concerning the Responsive Expert Report of Dr. Ian S. Mackay)***, with the Clerk of the Court using CM/ECF, which will send notification of such filing to the following counsel of record:

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I further certify that on April 14, 2008, I caused a copy of the foregoing sealed document to be served by e-mail and hand delivery on the above-listed counsel and on the following non-registered participants in the manner indicated:

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